UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION I

1 CONGRESS STREET, SUITE 1100, BOSTON, MASSACHUSETTS 02114-2023

MEMORANDUM

DATE: January 23, 2001

SUBJ: *Remedial Action Work Plan for Willow Brook and Willow Brook Pond, November 2000*

FROM: Kimberly Tisa, PCB Coordinator
Pesticides, Toxics, and Urban Program Unit

TO: Ernie Waterman, Project Manager
RCRA Corrective Action

I have reviewed the above referenced document (*Work Plan*) for the Pratt & Whitney (P&W) facility located at 400 Main Street, East Hartford, CT. The *Work Plan* describes the remedial activities that are proposed in the Willow Brook and Willow Brook Pond areas. The following comments are based on my review of this *Work Plan* as they pertain to the PCB Regulations:

GENERAL COMMENTS

1. As noted during our meetings, the driving factor for the remediation action levels is eco-risk. Under the TSCA regulations, remediations of this caliber and with the institutional controls proposed would require public participation, normally through a public notice/comment period. This has not yet occurred. As such, it must be clear to P&W that this remediation is, in effect, source removal with interim institutional controls and that P&W is undertaking the measure at its own risk. (Albeit as discussed on several occasions, it appears that what P&W is proposing is reasonable and will most likely pass this type of assessment.) Until we have a human health/eco-risk evaluation and public process, we can not consider the remedy permanent.

   Also, I can find no clear discussion on the piping and/or conduit discharging into the Willow Brook Ponds from the plant or upstream. I believe we had past discussions on these structures and that minimal to no contamination was found; however, it should be redocumented here.

2. I would suggest that P&W provide an analysis of the costs associated with the proposed remedy and its alternatives, including complete source removal.

3. EPA has developed Quality Assurance Guidelines for submission of Quality Assurance

3. EPA has developed Quality Assurance Guidelines for submission of Quality Assurance Project Plans (QAPP). For future sites and projects, I suggest this format be used in that it helps simplify and clarify analytical requirements, sampling methodologies, QA/QC specifications and laboratory requirements. I have enclosed a summary outline of this guidance document which may be obtained from EPA's OEME Quality Assurance office.

SPECIFIC COMMENTS

4. Page 7, 2nd complete paragraph - The text indicates that "free oil" was observed at WT-SB-88 at a depth of 10-12 feet. It is not clear if any sample of this product was collected and analyzed. If so, what were the results?

5. Page 9, Subsection 1.4.1 - The last sentence states that "SVOCs and select metals are co-located with the elevated PCB concentrations". It is unclear how P&W is making this determination. Drawings 1-3 show the constituents of concern and sampling points along Willow Brook and in Willow Pond; however, it appears that much of the analytical determinations were only for PCBs, not for these other constituents. Therefore, it is unclear how P&W can make this assertion. Further, at least one sampling location (e.g. WT-SD-47) shows relatively low levels of PCBs, but much higher levels of SVOCs.

6. Page 9, Subsection 1.4.2 - The text indicates that groundwater contamination will be monitored post-excavation and that new monitoring wells will be installed. There is no indication on the frequency and duration of this monitoring. (Work Plan addresses. See Page 19, Subsection 2.4.2.)

7. Page 10, Subsection 2.0, 3rd paragraph

   a. The text refers to the "PCB action level". This appears to be the driver for cleanup; however, from a cumulative standpoint the other constituents may also be problematic. (See Comment 5, above). Based on the information provided in subsequent sections, it appears that confirmation sampling will include the other constituents of concern; hoever, the target action levels for cleanup have not been provided.

   b. The 1st sentence states that the PCB action level assumes future use of the area as open pond flanked by parking and green space. This is slightly misleading as in the previous paragraph P&W indicates that a fence will be installed around the remediated area to preclude access to the area. In this event, the affected area will not be "open" to the public, but actually be a restricted area.

   c. The 2nd sentence states that if redevelopment involves a bike path or roadway, the area will be remediated so the PCBs are less than 1ppm. In our most recent meeting with P&W, I believe it was indicated that these redevelopment scenarios were no longer

under consideration. If so, the *Work Plan* should be amended and these options deleted. It should also be noted that any future change in the property use would require re-evaluation of the exposure risks and potentially additional remediation.

8. Page 14, Subsection 2.3.1, Decontamination

   a. 1st paragraph - The text indicates that pressure washing will be used for equipment decontamination. The PCB regulations at §761.79(b) and (c) specify decontamination allowances for sampling equipment. The proposed decontamination procedures do not meet any of the specified allowances.

   b. 2nd paragraph - This text refers to the Appendix B SOPs. In reviewing these SOPs, I note that many are very general in nature and are not specifically written for this project. EPA recommends that SOPS be written site specifically as this insures consistency throughout the project.

   c. 3rd paragraph - The text indicates that liquids generated during decontamination will be disposed of via the sanitary system. This is not sufficient. These liquids could contain COCs that exceed the allowable discharge limits under either or both the federal and state regulations. For example, decontamination waters generated during a PCB remediation must be disposed of as a TSCA-regulated material unless the waters are decontaminated in accord with §761.79(b). The discussion needs to be revised to discuss not only state requirements under the discharge permit, but also federal PCB requirements.

9. Page 15, Process Water Buildings - The last sentence refers to the abandonment of pipes and utilities. It any of these pipes/utilities are in contact with contaminated material, decontamination would be required. There is no discussion of this included in the text.

10. Page 15, 3rd and 4th paragraphs - These subsections refer to characterization for disposal of the oil/water separator the demolition debris. It any of the material in question contains PCBs and meets the definition of *PCB remediation waste* as defined at §761.3, the disposal requirements are specified under §761.61(b), unless otherwise requested under §761.(a) or (c). P&W must specify how these wastes will be managed.

11. Page 15, Subsection 2.3.3.

   a. 1st paragraph - The last sentence refers to a lime stabilization procedure to eliminate free-draining water. As discussed with P&W in previous meetings, the PCB regulations specifically prohibit solidification of liquids into non-liquids for purposes of avoiding disposal requirements. Given the types of impacted materials, namely sediments, there is likelihood that the excavated materials will be low in % solids. Some type of dewatering step will be necessary, such as gravity filtration, to remove

as much excess water from these sediments as reasonably feasible prior to solidification. (I believe this comment in addressed on Page 17 of the Work Plan; however, P&W should provide more detail on its implementation., such as how the water will be collected and stored, etc.)

b. 2nd paragraph - The text indicates that excavated areas will be restored with a geotextile, soil and stone cap. Since remediation will be performed in a phased approach, P&W should clarify how these institutional controls will be integrated to achieve an effective barrier to contamination.

c. 2nd paragraph - The text indicates that dewatering pumps will be used to pump water from the side of the dam that will be remediated. How will this water be handled? If P&W plans on "discharging" to the open side, it should clarify how it can insure that contaminated sediments will not be suspended into the water column during the dewatering.

12. Page 16, Dewatering - See Comment 8.c., above.

13. Page 16, Excavation Methods, 2nd paragraph - The last sentence should state "Excavation will continue...in excess of 25ppm within the pond and brook **and** 1ppm within the wetland are removed."

14. Page 17 - A map showing the staging, decontamination and waste storage areas should be provided.

15. Page 17,1st paragraph - See comment 8.c, above.

16. Page 17, Off-Site Disposal - Why is P&W proposing to dispose of this material at a solid waste landfill? Much of this material contains high concentrations of PCBs and other COCs. Disposal requirements for PCB remediation waste are found at §761.61(a), (b), and (c).

17. Page 18, Subsection 2.3.5, 4th paragraph - See comment 7.c, above.

18. Page 21, Subsection 4.1.2

a. The text states that "The sampling program will be implemented in accordance with 40 CFR Part 761 Section 761.61(c) and in general compliance with Subpart O. I have received no request for a risk-based sampling procedure under §761.61(c). If P&W is requesting a variation from the Subpart O requirements, a formal request must be made and an approval issued.

19. Page 22 - Remedial Action Field Sampling

    a. The SOP associated with Soil Sampling for VOCs is of concern.. The proposed SOP for soil VOC sampling indicates only that the sample must completely fill the sample container. EPA recommends that SW-846 Method 5035 be used for field collection of VOC samples. This minimizes the potential loss of contaminants prior to sample analysis.

20. Page 22, Subsection 4.2.2. - Given the heterogeneity of the contamination, the proposed grid interval for confirmatory sampling appears too large, especially given that P&W also proposes compositing up to 6 grab samples. Further P&W proposes an even larger area (1 per 2,400 ft^2) for confirmatory sampling of other COCs. P&W should provide a justification as to why it believes this sampling scheme is sufficient to ensure target action levels are met for all COCs.

21. Page 23, 1st sentence - The text indicates that additional confirmatory samples for metals, VOCs, SVOCs, and cyanide will be collected. In its investigatory phase, P&W identified several areas where elevated Total Petroleum Hydrocarbons were found. Will confirmatory analysis also include TPH? If so, it should be added and also included in Table 4-1.

22. Page 23, 2nd paragraph , sample collection procedures - EPA recommends that compositing be performed in the laboratory. Further, the PCB regulations require that analytical determinations be performed on, **not reported on**, a dry-weight analysis. Therefore, given the characteristics of the samples (wet sediments), I would recommend that aliquots of the individual grab samples be dried either at low temperature or at ambient temperature in a desiccator, prior to compositing. P&W may also wish to confirm with CTDEP that compositing of samples for confirmatory analysis will be allowed under the state regulations. The compositing discussion should also include a discussion on how the composite sample results will be interpreted.

23. Page 23, 4th paragraph - The text indicates that the sampling device will be decontaminated or replaced with new sampling equipment prior to sample collection. What criteria will be used to make this determination?

24. Page 23, 5th paragraph

    a. The 2nd sentence makes no sense. The text appears to indicate that field screening using test kits will be performed on those samples exceeding 25ppm. Please clarify.

    b. The 3rd sentence is misleading. The test kits don't identify the Aroclor present. Rather, the test kits quantify total PCBs, based on calibration with a specified Aroclor.

25. Page 24, Subsection 4.2.3

    a. The 1st paragraph indicates that disposal characterization samples will determine the appropriate method for handling and disposal. This is not allowed by the PCB regulations for PCB remediation waste. Specifically, the regulations require disposal based on the insitu PCB concentration, not the PCB concentration of the generated stockpile. The generator must select a PCB disposer based on the insitu characterization sampling; however, the disposer may require additional analytical based on its permit conditions and/or requirements.

    b. It is unclear based on the information presented if sufficient characterization samples exist that would allow segregation of lower-contaminated material from higher-contaminated material for off-site disposal. It would be helpful if P&W could specify what it proposes to do with the excavated-contaminated waste. This would enable us to better determine how much additional sampling, if any, would be needed.

    c. 2nd paragraph - Field screening may not be used for segregation purposes unless the field screening methodology has gone through comparison testing as specified under Subpart Q of 40 CFR Part 761. Unless the field screening method is validated, the methods specified in Subparts N and O are required.

26. Page 26, Subsection 4.5.1

    a. What is the disposition of the wastes described in this section?

27. Page 40, Subsection 5.7.4

    a. As discussed in comment 22, above, the PCB regulations require that PCB concentrations be determined on a dry-weight analysis, not reported on dry-weight.

28. Table 4-1

    a. The Table should specify the extraction method associated with each analytical method, if applicable.

    b. The method citation for PCBs is incorrect. The method number is 8082, but the Revision Date is **January, 1998** not January 1988.

    c. At a minimum, any wastewater generated during this remedial process must be tested for PCBs. See comment 8.c., above. This should be noted in the Table.

    d. See Comment 21, above.

e. It is unclear what the "Anticipated Number of Samples" column is based upon. For example, the Table indicates that 65 soil/sediment samples will be collected for confirmatory samples. Note 1 indicates that bottom samples will be collected at 1/400ft^2. Further, on Page 22, Subsection 4.2.2. P&W indicates that up to 6 grab samples will be composited for purposes of confirmatory analysis. Therefore, clarification is needed on how these samples numbers were derived.

f. EPA recommends that some bias sampling, based on visual observations, should be added to this list.

29. Table 4-2

a. The Table indicates that aqueous PE samples will be submitted to the laboratory. EPA recommends that in addition to aqueous PE samples, non-aqueous (e.g. solid) PE samples should also be submitted since the major portion of this project deals with soils/sediments.

30. Table 5-1

a. Methods specified in Table 5-1 do not correspond to those listed in Table 4-1.

b. The PCB PQLs for aqueous matrices is too high given that the decontamination standard for water is 0.5 µg/L (see 40 CFR §761.79(b)).

c. P&W should also confirm with its selected laboratory that it is capable of achieving the stated PQLs.

d. The selected laboratory's SOP numbers for the cited methods should also be included in this section. Also the laboratory's internal QA/QC requirements should be included.

31. Table 5-6

a. Duplicative of Table 4-3.

32. SOPs - See comment 8.b., above.

REGION I, EPA-NEW ENGLAND

COMPENDIUM OF QUALITY ASSURANCE

PROJECT PLAN REQUIREMENTS AND GUIDANCE

U.S. EPA-NEW ENGLAND
Region I
Quality Assurance Unit Staff
Office of Environmental Measurement and Evaluation

October 1999
Final

Preface

The Region I, EPA-New England Quality Assurance Unit has restructured its Quality Assurance Project Plan (QAPP) Program in response to the recently reissued EPA Order 5360.1 CHG 1, July 1998. Among other requirements, this "QA Order" requires the development, review and approval of QAPPs for all environmental data operations performed by or on behalf of EPA. The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. In addition, these requirements are incorporated into voluntary, consentual or unilateral enforcement agreements, decrees and orders. The Region I, EPA-New England Compendium of Quality Assurance Project Plan Requirements and Guidance and its attachments implement within EPA-NE the national QAPP requirements specified in "EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations", EPA QA/R-5, October 1998, or most recent revision, and the "EPA Quality Manual for Environmental Programs", 5360, July 1998.

As a Regional implementation document, the Region I, EPA-New England Compendium of Quality Assurance Project Plan Requirements and Guidance;

-outlines a Regional systematic planning process to ensure project quality objectives are appropriately identified
-defines a minimum set of project QA/QC activities and procedures to ensure that data collected for this Region are of known and documented quality and can be used in environmental decision making
-specifies project information that must be compiled and included in a QAPP to document that project activities have been properly planned
-and, assigns roles and responsibilities to project management/personnel and to EPA-NE to establish accountability.

REGION I, EPA-NEW ENGLAND COMPENDIUM OF QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS AND GUIDANCE

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A. REGION I, EPA-NEW ENGLAND QUALITY ASSURANCE PROJECT PLAN MANUAL, DRAFT, SEPTEMBER 1998

B. THE VOLUNTEER MONITOR'S GUIDE TO QUALITY ASSURANCE PROJECT PLANS, EPA 841-B-96-003, SEPTEMBER 1996

C. GENERIC QUALITY ASSURANCE PROJECT PLAN GUIDANCE FOR PROGRAMS USING COMMUNITY LEVEL BIOLOGICAL ASSESSMENT IN WADEABLE STREAMS AND RIVERS, EPA 841-B-95-004, JULY 1995

D. QUALITY ASSURANCE REQUIREMENTS FOR CONDUCTING BROWNFIELDS SITE ASSESSMENTS, DRAFT, OCTOBER 1996

REGION I, EPA-NEW ENGLAND COMPENDIUM OF QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS AND GUIDANCE

1.0 INTRODUCTION

A Quality Assurance Project Plan (QAPP) is a required planning document that provides a "blueprint" for obtaining the type, quantity and quality of data needed to support environmental decision making. The QAPP documents all quality assurance (QA), quality control (QC) and technical activities and procedures associated with planning, implementing and assessing all environmental data operations. EPA-New England (EPA-NE) recognizes the following two types of QAPPs:

- "Project-specific QAPPs" provide a QA "blueprint" specific to one project or task. Project-specific QAPPs are used when projects are limited in scope and time and, in general, can be considered the sampling and analysis plan/workplan for the project.

- "Generic program QAPPs" provide an overarching plan describing a program's quality objectives, and documents the comprehensive set of sampling, analysis, QA/QC, data validation and evaluation, and assessment Standard Operating Procedures (SOPs) specific to one program or group. In contrast to the project-specific QAPP, the generic program QAPP serves as an umbrella under which project-specific tasks may be conducted over an extended period of time. Project or task-specific information, not covered by the umbrella, is documented in detailed sampling and analysis plans/workplans, which use the generic program QAPP as an informational reference whenever appropriate.

EPA Order 5360.1 CHG 1 requires that a QAPP be prepared and approved for all environmental data operations performed by or on behalf of EPA prior to the initiation of those data operations. In addition to the QAPP requirement, this Order also mandates that documented Quality Systems be in place to support the development, review, approval, implementation and assessment of all environmental data operations and to ensure that environmental technologies are designed, constructed, and operated according to defined expectations. EPA-NE designates those organizations performing work for or on behalf of EPA as Lead Organizations and includes those organizations performing work in response to voluntary, consentual or unilateral enforcement agreements, decrees and orders. Lead Organizations must develop, operate and document their own Quality Systems in Quality Management Plans (QMPs) to ensure that environmental data acquired for the Agency are of known and documented quality and are suitable for their intended use.

For guidance in developing Quality Systems, refer to Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, American National Standard, ANSI/ASQC E4-1994; EPA Requirements for Quality Management Plans, EPA QA/R-2, October 1998 or most recent revision; and EPA Quality Manual for Environmental Programs, 5360, July 1998.

2.0 SCOPE

The Region I, EPA-NE Compendium of Quality Assurance Project Plan Requirements and Guidance (hereafter referred to as the *EPA-NE QAPP Compendium*) is based on Agency requirements as outlined in EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations,

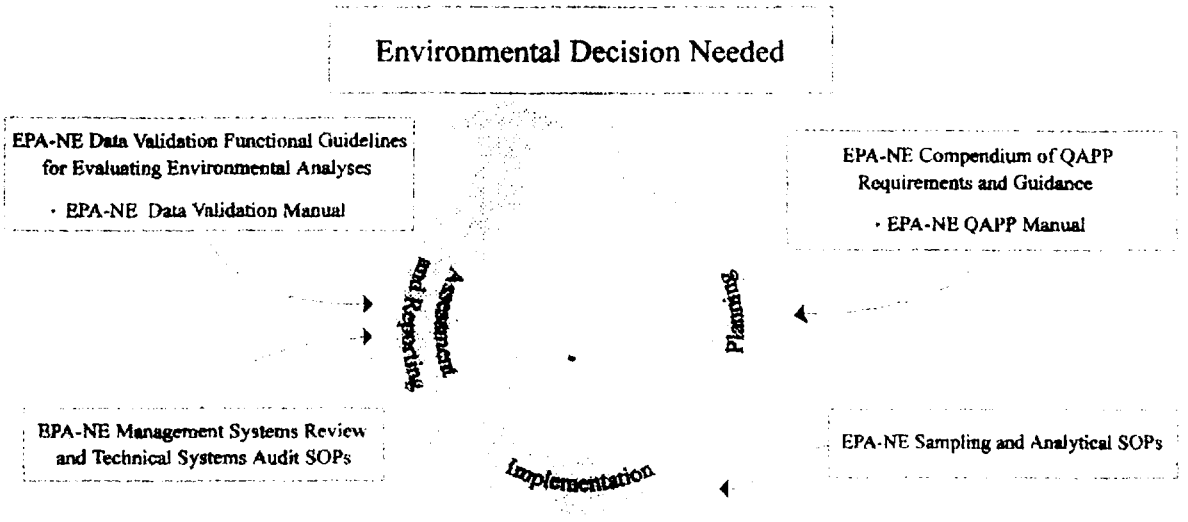


Figure 1 EPA-NE Quality System for Environmental Data Operations and Supporting EPA-NE Requirements and Guidance Documents

EPA QA/R-5, October 1998 or most recent revision. The *EPA-NE QAPP Compendium* provides the framework for all project-specific and generic program QAPPs prepared for environmental data operations conducted in EPA-NE. It is a companion document to other documents written by the Region 1, EPA-NE Quality Assurance Unit. These documents (refer to Figure 1) form the basis for the EPA-NE Quality System supporting Regional environmental data operations. These documents should be included in applicable interagency agreements and voluntary, consentual or unilateral enforcement agreements, decrees and orders.

Attachment A of the *EPA-NE QAPP Compendium*, the Region 1, EPA-New England Quality Assurance Project Plan Manual (hereafter referred to as the *EPA-NE QAPP Manual*) specifies requirements and provides comprehensive, detailed guidance for developing project-specific and generic program QAPPs. All actions, activities and procedural steps described as "must" in the *EPA-NE Compendium* and *EPA-NE QAPP Manual* are required. All actions, activities and procedural steps described as "should" in the *EPA-NE QAPP Compendium* and *EPA-NE QAPP Manual* are suggested but not required. The *EPA-NE QAPP Manual* must be used by EPA-NE and other Lead Organizations when performing environmental data operations. The *EPA-NE QAPP Manual* requires that specific QAPP elements be addressed and that specific project information, as itemized in Table 1, be included in the QAPP. QAPP Worksheets are provided in Appendix A of the *EPA-NE QAPP Manual* to help compile this critical project information. All applicable worksheet information must be incorporated directly into the QAPP as Tables, Flowcharts, Diagrams, Attachments, etc.

Additional QAPP guidance is provided in Attachments B through D of the *EPA-NE QAPP Compendium* and must be followed when so directed by the applicable EPA-NE program office. Even if program-specific guidance is followed (Att. B-D), the required QAPP elements and the information specified in Table 1 still must be included in the QAPP. Additional Agency program/initiative-specific QAPP guidance documents will be developed as needed.

Since the content and level of detail in individual QAPPs will vary according to the work being performed and the intended use of the data, EPA-NE supports a "graded approach" when preparing QAPPs. In other words, the degree of documentation and detail will vary based upon the complexity and cost of the project. Appropriate consideration should be given to the significance of the environmental problem to be investigated, the environmental decision to be made, and the impact on human health and the environment.

3.0 REQUIRED QAPP ELEMENTS

In accordance with EPA QA/R-5, there are four basic element groups that must be addressed in a QAPP, refer to Figure 2. In order to piece these interrelated elements together and to ultimately meet project objectives, the Region I Systematic Planning Process as outlined in Figure 1 of the *EPA-NE QAPP Manual* must be utilized and planning meetings (a.k.a. scoping meetings) must be held.

Specific requirements for each element group are detailed in Attachment A, the *EPA-NE QAPP Manual*, and in the program-specific guidance documents provided in Attachments B through D.

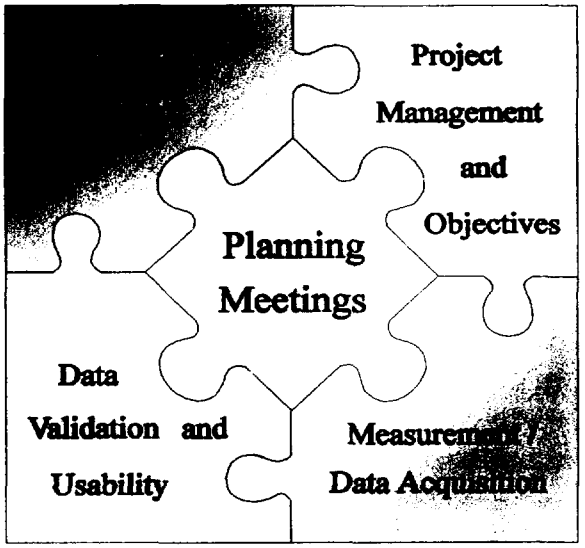
It is strongly recommended that generic program QAPPs and project-specific QAPPs be prepared using the format described in the attached *EPA-NE QAPP Manual* and sections titled accordingly. However, if some, or all, of the required QAPP elements are incorporated into other project planning documents (i.e., Sampling and Analysis Plans (SAPs), Field Sampling Plans (FSPs), Field Operations Plans (FOPs), Project Operations Plans (POPs) or General Project Workplans (WPs)), then a cross-reference table, similar to Table 1, must be provided to identify where each required QAPP element and all required information, as defined by the EPA-NE QAPP Worksheets, are located in the inclusive project document. The reference location must be exact and must specify the complete document title, date, section number, page numbers, and location of all QAPP elements and information in the inclusive document.

3.0 Assessment/Oversight

This element group details the procedures used to ensure proper implementation of the QAPP. It describes minimum requirements for QA Reports to Management and for Final Project Reports.

1.0 Project Management and Objectives

This element group encompasses all aspects of project management, objectives and background. It identifies the roles and responsibilities of project personnel, describes communication procedures and details the proposed project schedule.



4.0 Data Validation and Usability

This element group details the QA activities that will be performed to ensure that the collected data are scientifically defensible, properly documented, of known quality, and meet the project objectives. All analytical data collected for EPA-NE must be validated according to the most recent revision of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses. If alternate validation guidance and/or modifications to the EPA-NE validation criteria will be used, then this must be documented and justified in the QAPP. After data have been validated, the impact of sampling error and spatial variability must also be assessed. Prior to use in project decision making, data must be assessed for usability, and interpreted statistically for environmental trends.

2.0 Measurement/Data Acquisition

This element group describes the design and implementation of all measurement systems that will be used during the project. All sampling procedures, analytical methods/procedures, and data handling and documentation procedures are described completely. If standard operating procedures (SOPs) exist, then they are referenced and included as attachments to the QAPP. All quality control procedures, frequency requirements, acceptance criteria, and corrective action procedures associated with all methods/procedures are documented.

Figure 2. EPA-NE QAPP Elements

4.0 ROLES AND RESPONSIBILITIES

Lead Organization

Lead Organizations are those entities that are responsible and accountable for all phases of the environmental data operation. The Lead Organization may perform the project work directly or contract for field sampling and/or analytical services and/or data validation and/or data assessment and/or audits and assessments.

The Lead Organization is responsible for ensuring that there is an approved QAPP in place prior to beginning any environmental data operation. Also, the Lead Organization is responsible for ensuring that organization personnel, contractors and/or subcontractors perform project work as prescribed in the approved QAPP. To that end, Lead Organizations are responsible for planning and conducting internal assessments of project activities.

Lead Organizations may include the following:

- EPA-NE
- Other Government Agencies under interagency agreements and Memoranda of Understanding (MOUs) with EPA-NE
- States, Tribes and Local governments under financial agreements, including grants and cooperative agreements with EPA-NE
- Non-profit Organizations (e.g., Volunteer Organizations, Interstate Associations, etc.) under financial agreements with EPA-NE, including institutions of higher education and hospitals
- Regulated Facilities (e.g., potentially responsible parties) under voluntary, consentual or unilateral enforcement agreements, decrees and orders.

Project Manager

The Project Manager is responsible for directing and/or overseeing and coordinating all project activities for the Lead Organization. He/she is responsible for submitting QAPPs and QAPP revisions and amendments to appropriate personnel, with sufficient lead time, for review and approval. QAPPs should be submitted to the approval authority for review and approval no less than 30 days in advance of the scheduled environmental data operation. The Project Manager must ensure that all technical issues identified during QA review are satisfactorily addressed and documented prior to beginning the data collection activity. The Project Manager is also responsible for reviewing the QAPP annually and documenting this review in a letter to the approval authority. Refer to Figure 3 for an outline of the QAPP development process.

Case Team

The Project Manager assembles a Case Team consisting of technical personnel including data generators, QA scientists, and data users to plan the project. The size of the Case Team should reflect the complexity of the project. For example, small volunteer monitoring projects may have Case Teams comprised of only two or three people.

Planning (scoping) meetings are convened to identify project objectives; environmental questions that must be answered; project Action Limits; the type and quantity of data; and how "good" the data must be (the data quality) to ensure that scientifically defensible environmental decisions are made. The

Case Team defines the quality of the data by setting acceptability limits for the project, otherwise known as measurement performance criteria. Once measurement performance criteria have been decided upon, the Case Team can select sampling and analytical methods that have appropriate quantitation limits and quality control limits to achieve project objectives.

The Case Team is responsible for compiling all project information as defined in the *EPA-NE QAPP Manual* and on the EPA-NE QAPP Worksheets and resolving all technical issues prior to the preparation of the QAPP document. **Ultimately, it is the responsibility of the project Case Team, not the QAPP preparer alone, to design a QA "blueprint" that meets project objectives.**

QAPP Preparation Team/Writer

The QAPP should be written by a team/person that has been involved in the project planning phase. Members of the QAPP Preparation Team should be experienced in many aspects of environmental science, including chemistry, engineering, hydrogeology and risk assessment. In addition, the QAPP Preparation Team should have experience with the sample collection procedures, analytical methods and data evaluation and assessment procedures that will be used for the project.

Project Personnel

An organizational chart must clearly show the reporting relationships between EPA-NE and project personnel from the Lead Organization, including contractors and subcontractors.

All project personnel are responsible for reading and understanding the QAPP before beginning field work. All individuals that have project responsibilities must sign a Project Personnel Sign-off Sheet (EPA-NE QAPP Worksheet #4) to document that they have read all relevant portions of the QAPP.

All project personnel are responsible for implementing the QAPP as prescribed.

EPA-NE QA UNIT

The EPA-NE QA Unit is responsible for reviewing and approving all intramural and extramural QAPPs, except in the case where the review and approval authority has been delegated by the EPA-NE Regional Quality Assurance Manager (RQAM) to:

- A non-EPA partner organization such as a State, Tribe, or other Federal Agency.

  Delegation of this authority to a non-EPA organization is contingent upon having an EPA-approved Quality Management Plan (QMP). An EPA-approved QMP documents that the organization has an acceptable Quality System to support all technical operations, including environmental data operations and environmental technology operations.

- An EPA-NE program (i.e., Superfund, RCRA).

  Delegation of this authority to an EPA-NE program is documented in the Region I QMP. In addition, the program is responsible for providing to the QA Unit copies of the completed QAPP "Title and Approval Page" and copies of DQO/PQO Summary Forms prior to the initiation of environmental data operations.

5.0 QAPP REVIEW AND APPROVAL

Internal Review and Approval

- The QAPP should undergo internal review at all levels. The Lead Organization is responsible for ensuring that the QAPP includes all required QAPP elements and information in accordance with Table 1 of this document and that project quality objectives (PQOs), technical activities and related QA/QC will result in data of known and documented quality that can be used in environmental decision making. To that end, the Lead Organization is responsible for performing a completeness check and should require that organizational personnel, contractors, and subcontractors review applicable sections of the QAPP to ensure technical adequacy of the document prior to submitting it to EPA-NE (or the delegated approval authority, if applicable).

External Review and Approval

- In accordance with EPA Order 5360.1 CHG 1, EPA-NE must review and approve all intramural and extramural QAPPs before environmental data operations can begin. This Order specifies that the authority to review and approve QAPPs may be delegated to a partner organization such as a State, Tribe, or other Federal Agency. Delegation of this authority by the EPA-NE RQAM is contingent upon that organization having an acceptable Quality System documented in an EPA-approved Quality Management Plan (QMP).

- EPA-NE requires all QAPPs to be complete and technically adequate. To that end, a Level 1 QAPP Completeness Check is performed to ensure that all required QAPP elements and information, as specified in Table 1 of this document, are present in the QAPP. When a QAPP is deemed complete, a Level 2 Technical QAPP Review is performed to ensure that project quality objectives, technical activities and related QA/QC will result in data of known and documented quality that can be used in environmental decision-making.

- All comments provided by EPA-NE (or the delegated approval authority, if applicable) must be acceptably addressed in writing before environmental data operations can begin. The response document (either a revised QAPP or letter responding to specific deficiencies) should contain complete identifying information, as it is presented on the original QAPP Title and Approval Page, with updated signatures and dates. Any revisions to the original QAPP document should be identified with a red-line or side bar to expedite document review and approval.

6.0 IMPLEMENTATION OF APPROVED QAPP

The approved QAPP must be implemented as prescribed, however, the QAPP may be modified at any time, after undergoing the proper approval process, to ensure project objectives are met.

7.0 REVISION AND MODIFICATION OF APPROVED QAPP

Project-specific QAPPs and generic program QAPPs are approved for a fixed period of time, specific to the environmental data operation. Project-specific QAPPs and generic program QAPPs must be kept current and revised whenever necessary, or when so directed by the approval authority, or at a minimum of every five years until the project is completed.

7.1 ANNUAL REVIEW OF APPROVED QAPP

Approved project-specific QAPPs and approved generic program QAPPs must be reviewed annually by the Lead Organization, and this annual review must be documented in a letter to the appropriate approval authority. If minor revisions are made to the approved QAPP that do not require reapproval (i.e., revisions do not impact data quality), then these minor revisions must be documented in either a letter that outlines the revisions or in a revised QAPP document. Likewise, if minor revisions are made to the approved QAPP that do require reapproval, then these minor revisions must be documented in either a letter that outlines the revisions or in a revised QAPP document and must be submitted for review and reapproval. If extensive revisions are necessary (i.e., greater than 10 pages and/or there are multiple impacts on data quality) requiring reapproval, then a revised QAPP document must be submitted for review and reapproval.

7.2 MODIFICATION OF APPROVED QAPP

When procedures and/or activities described in the original QAPP must be modified immediately to achieve project objectives, then the QAPP must be amended. This amendment must be reviewed and approved in the same manner as the original QAPP. The amendment should contain complete identifying information, as presented on the original QAPP Title and Approval Page, with updated signatures and dates. Only after the amendment has been approved can the change be implemented.

Verbal approval of modifications may be obtained to expedite project work. Descriptions of modifications and verbal approvals must be documented in telephone logs which are retained in the project file. Subsequently, this verbally approved modification must be documented in an amendment to the QAPP and submitted to EPA-NE (or other approval authority, if applicable) within 7 working days for formal signature approval.

8.0 QAPP ARCHIVAL

All QAPPs, including reviewers' comments and responses to reviewers' comments (revised QAPPs, QAPP amendments, and response letters addressing specific issues) must be archived in the appropriate project/program file according to the procedures specified by the Lead Organization in the QAPP and/or their QMP.

Project files must be retained for the period of time specified in the interagency agreement, MOU, cooperative agreement, financial agreement, contract, or voluntary, consentual or unilateral enforcement agreement, decree or order.

EPA-NE retains the authority to request project/program files for any extramural project/program during the period of performance of the extramural agreement.

9.0 REFERENCES

1. Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, American National Standard, ANSI/ASQC E4-1994.

2. EPA Requirements for Quality Management Plans, October 1998, (EPA QA/R-2)
Website: http://es.epa.gov/ncerqa/qa/index.html

3 EPA Quality Manual for Environmental Programs, 5360, July 1998
Website: http://es.epa.gov/ncerqa/qa/index.html

4. March 2, 1999 Memorandum From Norine E. Noonan (AA) to Assistant Administrators and Regional Administrators Re: Clarification of Terminology for the EPA Quality System with attachments

5. EPA Requirements for Quality Assurance Project Plans, October 1998, (EPA QA/R-5)
Website: http://es.epa.gov/ncerqa/qa/index.html

6. EPA Guidance for Quality Assurance Project Plans, Draft Final-July 1998, (EPA QA/G-5)
Website: http://es.epa.gov/ncerqa/qa/index.html

7. Guidance for the Data Quality Objective Process, EPA/600/R-98/018, February 1998, (EPA QA/G-4)
Website: http://es.epa.gov/ncerqa/qa/index.html

8. Region I, Quality Assurance Management Plan, Revision 2, Approved by EPA's Quality Assurance Division 10/24/96

9. Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses, December 1996
Website: http://www.epa.gov/region01/oeme/toc.html
Contact: Dr. Steve Stodola, EPA-NE OEME, 781-860-4634

10. Guidance for the Preparation of Standard Operating Procedures for Quality-Related Operations, EPA/600/R-96/027, November 1995, (EPA QA/G-6)
Website: http://es.epa.gov/ncerqa/qa/index.html

11. Guidance for Data Quality Assessment: Practical Methods for Data Analysis, EPA/600/R-96/084, January 1998, (EPA QA/G-9)
Website: http://es.epa.gov/ncerqa/qa/index.html

12. National Enforcement Investigations Center (NEIC) Policies and Procedures, EPA-330/9-78-001-R, May 1978, Rev. December 1981
NTIS: 1-800-553-6847

13. The Volunteer Monitor's Guide To Quality Assurance Project Plans, EPA/841/B-96/003, September 1996

14. Generic Quality Assurance Project Plan Guidance for Programs Using Community Level Biological Assessment in Wadeable Streams and Rivers, EPA/841/B-95/004, July 1995
Website: http://www.ntis.gov/index.html
NTIS: 1-800-553-6847

15. Implementation of Quality Assurance Requirements for Organizations Receiving EPA Financial Assistance
Website: http://www.epa.gov/ogd/qa.htm

Figure 3. Outline of QAPP Development

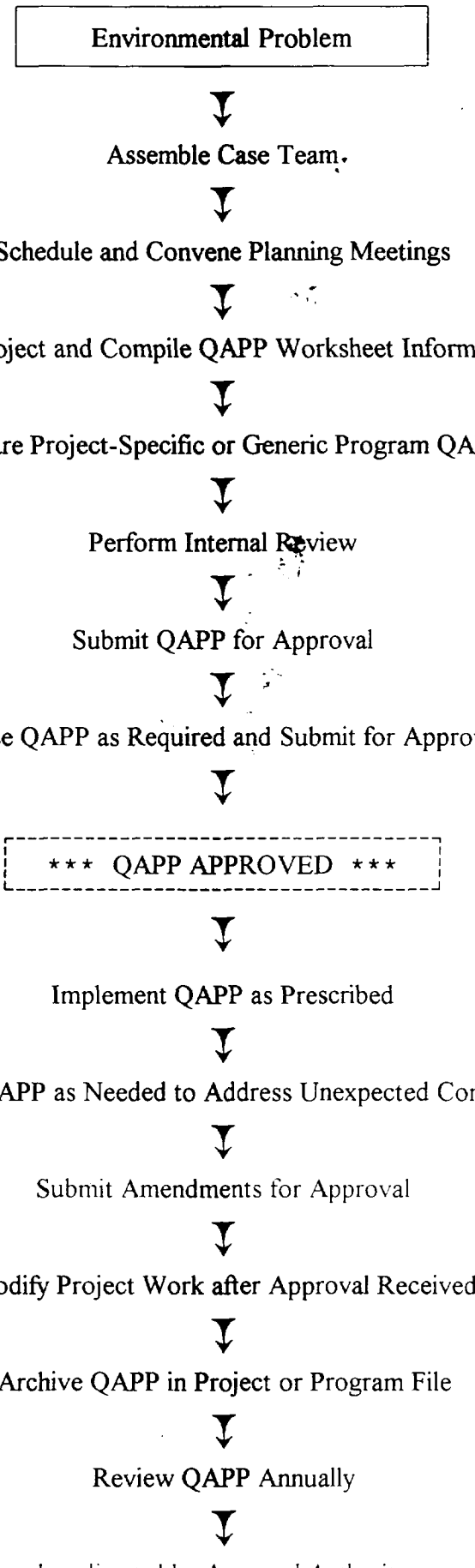


Table 1. Region I, EPA-NE QAPP Requirement Summarization

EPA QA/R-5 QAPP ELEMENTS	REQUIRED EPA-NE QAPP ELEMENTS and CORRESPONDING EPA-NE QAPP SECTIONS	EPA-NE QAPP Worksheet #	REQUIRED INFORMATION
Project Management and Objectives			
A1	1.0 Title and Approval Page	1	- Title and Approval Page
A2	2.0 Table of Contents and Document Format 2.1 Table of Contents 2.2 Document Control Format 2.3 Document Control Numbering System 2.4 EPA-NE QAPP Worksheet #2	2	- Table of Contents - EPA-NE QAPP Worksheet
A3	3.0 Distribution List and Project Personnel Sign-off Sheet	3 4	- Distribution List - Project Personnel Sign-off Sheet
A4, A8	4.0 Project Organization 4.1 Project Organizational Chart 4.2 Communication Pathways 4.2.1 Modifications to Approved QAPP 4.3 Personnel Responsibilities and Qualifications 4.4 Special Training Requirements/ Certification	5a 5b 6 7	- Organizational Chart - Communication Pathways - Personnel Responsibilities and Qualifications Table - Special Personnel Training Requirements Table
A5	5.0 Project Planning/Project Definition 5.1 Project Planning Meetings 5.2 Problem Definition/Site History and Background	8a 8b	- Project Scoping Meeting Attendance Sheet with Agenda and other Project Planning Meeting Documentation - Problem Definition/Site History and Background - EPA-NE DQO Summary Form - Site Maps (historical and present)
A6	6.0 Project Description and Schedule 6.1 Project Overview 6.2 Project Schedule	9a 9b 9c 9d 10	- Project Description - Contaminants of Concern and Other Target Analytes Table - Field and Quality Control Sample Summary Table - Analytical Services Table - System Designs - Project Schedule Timeline Table
A7	7.0 Project Quality Objectives and Measurement Performance Criteria 7.1 Project Quality Objectives 7.2 Measurement Performance Criteria	11a 11b	- Project Quality Objectives/Decision Statements - Measurement Performance Criteria Table
Measurement/Data Acquisition			
B1	8.0 Sampling Process Design 8.1 Sampling Design Rationale	12a 12b	- Sampling Design and Rationale - Sampling Locations, Sampling and Analysis Method/SOP Requirements Table - Sample Location Map

EPA QA/R-5 QAPP ELEMENTS	REQUIRED EPA-NE QAPP ELEMENTS and CORRESPONDING EPA-NE QAPP SECTIONS	EPA-NE QAPP Worksheet #	REQUIRED INFORMATION
B2, B6, B7, B8	9.0 Sampling Procedures and Requirements 9.1 Sampling Procedures 9.2 Sampling SOP Modifications 9.3 Cleaning and Decontamination of Equipment/Sample Containers 9.4 Field Equipment Calibration 9.5 Field Equipment Maintenance, Testing and Inspection Requirements 9.6 Inspection and Acceptance Requirements for Supplies/ Sample Containers	13 12b 14 15	- Sampling SOPs - Project Sampling SOP Reference Table - Sampling Container, Volumes and Preservation Table - Field Sampling Equipment Calibration Table - Cleaning and Decontamination SOPs - Field Equipment Maintenance, Testing and Inspection Table
B3	10.0 Sample Handling, Tracking and Custody Requirements 10.1 Sample Collection Documentation 10.1.1 Field Notes 10.1.2 Field Documentation Management System 10.2 Sample Handling and Tracking System 10.3 Sample Custody	16	- Sample Handling, Tracking and Custody SOPs - Sample Handling Flow Diagram - Sample Container Label (Sample Tag) - Chain-of-Custody Form and Seal
B4, B6, B7, B8	11.0 Field Analytical Method Requirements 11.1 Field Analytical Methods and SOPs 11.2 Field Analytical Method/SOP Modifications 11.3 Field Analytical Instrument Calibration 11.4 Field Analytical Instrument/ Equipment Maintenance, Testing and Inspection Requirements 11.5 Field Analytical Inspection and Acceptance Requirements for Supplies	17 18 19	- Field Analytical Methods/SOPs - Field Analytical Method/SOP Reference Table - Field Analytical Instrument Calibration Table - Field Analytical Instrument/Equipment Maintenance, Testing and Inspection Table
B4, B6, B7, B8	12.0 Fixed Laboratory Analytical Method Requirements 12.1 Fixed Laboratory Analytical Methods and SOPs 12.2 Fixed Laboratory Analytical Method/SOP Modifications 12.3 Fixed Laboratory Instrument Calibration 12.4 Fixed Laboratory Instrument/ Equipment Maintenance, Testing and Inspection Requirements 12.5 Fixed Laboratory Inspection and Acceptance Requirements for Supplies	20 21	- Fixed Laboratory Analytical Methods/SOPs - Fixed Laboratory Analytical Method/SOP Reference Table - Fixed Laboratory Instrument Maintenance and Calibration Table
B5	13.0 Quality Control Requirements 13.1 Sampling Quality Control 13.2 Analytical Quality Control 13.2.1 Field Analytical QC 13.2.2 Fixed Laboratory QC	22a 22b 23a 23b 24a 24b	**Sampling** - Field Sampling QC Table - Field Sampling QC Table cont. **Analytical** - Field Analytical QC Sample Table - Field Analytical QC Sample Table cont. - Field Screening/Confirmatory Analysis Decision Tree - Fixed Laboratory Analytical QC Sample Table - Fixed Laboratory Analytical QC Sample Table cont.

EPA QA/R-5 QAPP ELEMENTS	REQUIRED EPA-NE QAPP ELEMENTS and CORRESPONDING EPA-NE QAPP SECTIONS	EPA-NE QAPP Worksheet #	REQUIRED INFORMATION
B9	14.0 Data Acquisition Requirements	25	- Non-Direct Measurements Criteria and Limitations Table
A9, B10	15.0 Documentation, Records and Data Management 15.1 Project Documentation and Records 15.2 Field Analysis Data Package Deliverables 15.3 Fixed Laboratory Data Package Deliverables 15.4 Data Reporting Formats 15.5 Data Handling and Management 15.6 Data Tracking and Control	26	- Project Documentation and Records Table - Data Management SOPs
Assessment/Oversight			
C1	16.0 Assessments and Response Actions 16.1 Planned Assessments 16.2 Assessment Findings and Corrective Action Responses 16.3 Additional QAPP Non-Conformances	27a 27b 27c	- Assessment and Response Actions - Project Assessment Table - Project Assessment Plan - Audit Checklists
C2	17.0 QA Management Reports	28	- QA Management Reports Table
Data Validation and Usability			
D1	18.0 Verification and Validation Requirements		- Validation Criteria Documents *
D2	19.0 Verification and Validation Procedures	29a 29b 29c	- Data Evaluation Process - Data Validation Summary Table - Data Validation Modifications
D3	20.0 Data Usability/Reconciliation with Project Quality Objectives	30	- Data Usability Assessment

* Include Data Validation Criteria Document as an attachment to the QAPP if Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses will not be used for validating project data.

Note: Required project-specific information should be provided in tabular format, as much as practicable. However, sufficient written discussion in text format should accompany these tables. Certain sections, by their nature, will require more written discussion than others. In particular, Section 8.0 should provide an in-depth explanation of the sampling design rationale and Sections 18-20 should describe the procedures and criteria that will be used to verify, validate and assess data usability.